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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,919	10/05/2006	Heino Hermeking	460-38	2573
81099	7590	03/03/2009		
Thomas M. Galgano 20 W. Park Avenue Suite 204 Long Beach, NY 11561			EXAMINER GOSART, TIMOTHY J	
			ART UNIT 4118	PAPER NUMBER
			MAIL DATE 03/03/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/555,919	Applicant(s) HERMEKING, HEINO	
	Examiner TIMOTHY GOSART	Art Unit 4118	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/07/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This office action is responsive to the amendment filed on November 7, 2005 . As directed by the amendment: claims 1-12 have been amended, no claims have been cancelled and no claims have been added. Thus, claims 1-12 are presently pending in this application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 2, 9, 10, and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Regarding Claim 1, the phrase "the latter" in Line 6 renders the claim indefinite because it is unclear which limitation the phrase is referring to.

5. Regarding Claims 2 and 9, the phrase "it" renders the claim indefinite because it is unclear which limitation the phrase is referring to.

6. Regarding claims 9 (Line 2 and Line 3), 10, and 12, the phrase "can be" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

7. Claim 12 recites the limitation "the fixation ring" in Line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Silvestrini (US 20020010510).

10. Regarding Claim 1, as best understood, Silvestrini discloses a diaphragm (Figure 4) that creates an artificial pupil in the anterior section of the eye (Paragraph 136) and which consists essentially of rigid planar elements 24 and 28 (Paragraph 153) that are divided on a fold line 38 (Figure 10) and there is an adhesive (“bondable”) connection of planar elements at the division by elastic polymers (Paragraph 153). This adhesive connection and folding mechanism make the device capable of being folded in half and unfolding to its original position due to its elasticity.

11. Regarding Claim 2, as best understood, Silvestrini discloses fold line 38 as being a straight line (Figure 10).

12. Regarding Claim 3, Silvestrini discloses the diaphragm as having a single fold line 38 across the diaphragm (Figure 10).

13. Regarding Claim 4, Silvestrini discloses the diaphragm as having two parallel joints 42 and 44 (Figure 13 and Paragraph 157) that are capable being folded at the joints.

14. Regarding Claim 6, Silvestrini discloses the elastic polymer at planar element division as being a material selected from an exemplary group (Paragraph 152), including pHEMA, a hydrophilic acrylate (Paragraph 148).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 5 and 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silvestrini (US 20020010510) in view of Hermeking (US 6221106).

17. Regarding Claim 5, Silvestrini discloses all of the claimed elements, including that the planar elements consist of PMMA (Paragraph 148), does not disclose the PMMA being dyed. However, Hermeking teaches planar elements of a diaphragm as consisting of dyed PMMA (Column 5, Lines 13-14). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to include in the Silvestrini device dyed PMMA as taught by Hermeking, for the purpose of providing an artificial iris of a color consistent with a native iris.

18. Regarding Claims 7-8, Silvestrini discloses all of the claimed elements except for the planar elements comprising round holes close to the edge and on both sides of the division. However, Hermeking teaches round holes 22 and 24 close to the edge of the planar elements 12 and 18 and on both sides of a division between planar elements (Figure 6). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to include in the Silvestrini device round holes in the planar elements as taught by Hermeking, for the purpose of providing an interface for a guiding proper device placement.

19. Regarding Claims 9-11, as best understood, Silvestrini discloses all of the claimed elements except for a fixation ring for insertion into the circular central opening of the

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diaphragm. However, Hermeking discloses a fixation ring 30 comprising central circular aperture 36 (Figures 11-12) for insertion into a central aperture of the diaphragm (Column 2, Lines 38-41). Hermeking also discloses stress-free implantation of the iris prosthesis system (Abstract), necessitating the fixation ring to constructed of a foldable material in the same manner as the diaphragm. Further, the fixation ring is PMMA (Column 4, Lines 24-31), which is foldable (Column 5, Lines 17-21). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to include in the Silvestrini device a round foldable fixation ring as taught by Hermeking, for the purpose of providing adequate latching of more than one diaphragm and appropriate artificial pupil shape.

20. Regarding Claim 12, as best understood, Silvestrini discloses all of the claimed elements except for a lens clipped into the central aperture of the fixation ring. However, Hermeking the diaphragm as being coupled to an artificial lens (Abstract) and being clipped to the central aperture of the fixation ring (Column 4, Lines 25-32). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to include in the Silvestrini device a lens clipped into the fixation ring as taught by Hermeking, for the purpose of providing secure attachment of the replacement lens.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Schanzlin et al (US 20040073303) discloses a corneal insert system comprising at least three inserts packaged and implanted individually or in combination and further discloses the use of hydrophilic acrylates such as pHEMA for implantation in the human eye.

Barber (US 5489301) discloses a diaphragm comprising various anchoring and fixation mechanisms.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY GOSART whose telephone number is (571)270-7826. The examiner can normally be reached on Monday-Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Quang Thanh can be reached on (571)272-4982. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. G./
Examiner, Art Unit 4118

/Quang D. Thanh/
Supervisory Patent Examiner, Art Unit
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